

In re Application of:

Vale et al.

Application No.: 09/502,664

Filed: February 11, 2000

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## **II. REMARKS**

Upon entry of the amendment, claims 1, 3 to 12 and 104 will be pending. A marked version showing the amendments to the specification and the claims is attached as Exhibit A for the Examiner's review.

### **A. Regarding the Amendments**

The specification was amended at page 1 to insert the serial number of the priority application. As such, the amendment merely addresses a formality, and does not add new matter.

Pursuant to the restriction requirement, claims 13 to 103 have been canceled herein with disclaimer, and without prejudice to Applicants' pursuing prosecution of subject matter encompassed within one or more of the claims in an application claiming the benefit of priority of the subject application. Claim 2 also has been canceled herein with disclaimer, and without prejudice.

Claim 1 has been amended to more clearly indicate that a modified FIAsh compound is "modified by acylation with an amino acid" and that the compound can be "a tautomer, anhydride or salt of said modified FIAsh compound". The amendments are supported, for example, by claim 2 as originally filed, and at page 3, line 24, to page 4, line 2. As such, the amendments do not add new matter.

Claim 4 has been amended to insert the Sequence Identifier for the recited amino acid sequence. The amendment, merely addresses a formality, is supported at page 4, lines 16-24, and, therefore, does not add new matter.

Claim 8 has been amended to use the recited trademarked names as adjectives, thus preserving their proprietary value. The amendments, which are supported at page 28, lines 5-6, merely address a formality, and do not add new matter.

New claim 104 has been amended. The new claim is supported, for example, at page 7, lines 4-5, and, therefore, does not add new matter.

### **B. Regarding the Species Election**

It was requested in Paper No. 6 that a species of solid support from among the solid supports recited in claims 8, 41, 50, 62, 67, 83, and 92 be elected, depending on the election pursuant to the restriction requirement. In response, the claims of Group I were elected, however, the species election was traversed because there was no reason set forth in Paper No. 6 for requiring such an election or to support the request to elect a species, and because, while the species as set forth are independent and patentably distinct, the various solid supports share a commonality of operation, function and effect with respect to the present invention (MPEP § 806.04(e)). Specifically, the solid supports merely are used as a medium to contain a FLASH binding compound, for example, in a chromatography method.

In the present Office Action, there is again no reason set forth for requiring the species election. Although the Examiner acknowledges that Applicants made the argument regarding the commonality of operation, function and effect, there again is no reason set forth for requiring such an election. The Examiner directs the Applicants' attention "to MPEP Chapter 800 where it is stated that a restriction requirement is proper...." (Office Action at page 3). However, the issue under consideration is not a 'restriction requirement' but a 'species election'; the standard for requiring a species election is not the same as that for a restriction requirement. Accordingly, for the reasons of record, it is respectfully maintained that the species election is not proper because of the commonality of operation, function and effect of the various recited solid supports and, therefore, requested that the species election be withdrawn.

### **C. Regarding the Declaration**

It was pointed out in the Office Action that changes made by an inventor to the Declaration were not dated and initialed. A copy of the Declaration was forwarded to the inventor, who initialed ("M.M.") and dated (as of the date it was reviewed and initialed, i.e., "Dec/15/01") the Declaration as an indication that the original changes were made by her. A copy of the initialed and dated

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Declaration is enclosed herewith and, therefore, it is respectfully requested that this objection be withdrawn.

**D. Regarding the Specification**

The specification is objected to as not citing the Serial No. of the priority application. The specification has been amended to address this formality and, therefore, it is respectfully requested that this objection be withdrawn.

**E. Regarding the Claim Objection**

Claims 4 to 7 are objected to as referring to an amino acid sequence without reciting a Sequence Identifier. Claim 4 has been amended to address this formality and, therefore, it is respectfully requested that this objection to the claims be withdrawn.

**F. Rejections under 35 U.S.C. § 112**

The rejections of claims 1 to 12 under 35 U.S.C. § 112, second paragraph, as allegedly vague and indefinite are respectfully traversed.

It is stated in the Office Action that claim 1 is indefinite for referring to a "modified FIAsh" and a "modified polypeptide" because the claim does not recite how the FIAsh or the polypeptide are modified. With respect to the term "modified FIAsh compound", although it is submitted that the subject matter would be understood by one skilled in the art viewing the specification, the claim nevertheless has been amended to more clearly refer to the modified FIAsh compound. As such, it is requested that this ground of rejection be removed.

With respect to the term "modified polypeptide", Applicants point out that the claim does not refer to a "modified polypeptide" but, instead, clearly states that a "polypeptide of interest, which has been modified to contain a FIAsh target sequence motif" (emphasis added). As such, the claim language indicates the specific type of 'modification' that the polypeptide contains. Furthermore, the meaning of a "FIAsh target sequence motif" would be clearly understood by the skilled artisan

because such target sequence motifs are well known in the art (see, for example, U.S. Pat. No. 6,008,378, which was cited by the Examiner for prior art purposes; see Abstract, paragraph bridging columns 3-4, and column 8, line 41, to column 9, line 45). Accordingly, it is requested that this ground of rejection be removed.

It is stated that claim 1 also is indefinite in referring to a "solid support" because the claim does not recite the type of solid support. It appears that this rejection is based on the species election. However, for the reasons set forth above, it is submitted that the species election is improper and unsupported, and should be removed. As such, it is requested that the rejection be removed for the reasons set forth in Section II.B, above. Furthermore, it is submitted that the term "solid support" would be clearly understood by one skilled in the art of protein purification and that the skilled artisan would recognize that the term "solid support" can refer to any of various different materials, such as those recited in claim 8, as are commonly used in the art. Accordingly, it is respectfully requested that this ground of rejection be removed.

It is also stated in the Office Action that claims 4 to 7 are indefinite as not providing a Sequence Identifier for the recited amino acid sequence. Claim 4 has been amended to include reference to SEQ ID NO:1, which shows the recited sequence. Claims 5 to 7 do not recite the sequence, but depend from claim 4. In view of the amendment to claim 4, it is submitted that claims 4 to 7 are clearly defined and, therefore, requested that this ground of rejection be removed.

It is further stated in the Office Action that claim 8 is indefinite in referring to Nylon<sup>TM</sup> and Teflon<sup>TM</sup>. The claim has been amended to preserve the proprietary rights associated with the trademarked terms. As such, it is requested that this ground of rejection be removed.

In summary, it is submitted that, in view of the amended claims and of knowledge in the art, one skilled in the art would know the scope of the subject matter regarded as the invention.

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Accordingly, it is respectfully requested that the rejections of the claims under 35 U.S.C. § 112, second paragraph, be removed.

### **G. Prior Art Rejections**

The rejection of claims 1, 4 to 7 and 9 to 12 under 35 U.S.C. § 102(a) as allegedly anticipated by U.S. Pat. No. 6,008,378 ("the '378 Patent") is respectfully traversed.

It is stated in the Office Action that the '378 Patent describes a FIAsh compound, and modified forms thereof. However, the '378 Patent does not teach or suggest a FIAsh compound, which is modified by acylation with an amino acid, as required by the claims. Accordingly, it is respectfully requested that the rejection of claims 1, 4 to 7 and 9 to 12 as allegedly anticipated by the '378 Patent be removed.

The rejection of claims 1, 4 to 7 and 9 to 12 under 35 U.S.C. § 102(b) as allegedly anticipated by Griffen et al. is respectfully traversed.

It is stated that Griffen et al. describe a FIAsh compound, which interacts with proteins tagged with a Cys-Cys-X-X-Cys-Cys sequence, and the use of dithiols such as EDT to facilitate purification of protein. However, the '378 Patent does not teach or suggest a FIAsh compound, which is modified by acylation with an amino acid, as required by the claims. Accordingly, it is respectfully requested that the rejection of claims 1, 4 to 7 and 9 to 12 as allegedly anticipated by Griffen et al. be removed.

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The Examiner is invited to contact Applicants' undersigned representative if there are any questions relating to this application. Accompanying this response is a petition for two-months extension of time and the required fee. The Commissioner is authorized to charge any additional fees that may be required, or credit any overpayments, to Deposit Account No. 50-1355.

Respectfully submitted,

Dated: April 25, 2002



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**EXHIBIT A**

**MARKED VERSION SHOWING AMENDMENTS TO  
THE SPECIFICATION AND CLAIMS**

TECH CENTER 1600/2900

**A. In the Specification**

The paragraph at page 1, lines 5-7, was amended as follows:

This application claims priority under 35 USC 119(e)(1) to [US] U.S. Provisional Patent application Serial No. [60/\_\_\_\_\_] 60/178,054, filed January 24, 2000, incorporated herein in its entirety.

**B. In the Claims**

The claims have been amended as follows:

1. (Amended) A method for isolating a polypeptide of interest comprising:
  - a) contacting a modified Fluorescein arsenical helix binder (FLAsH) compound, which has been modified by acylation with an amino acid, or a tautomer, anhydride or salt of said modified FLAsH compound, immobilized on a solid support with a solution containing a polypeptide of interest, which has been modified to contain a FLAsH target sequence motif, under conditions that allow binding of the polypeptide to the immobilized FLAsH compound; and
  - b) eluting the polypeptide of interest from the immobilized FLAsH compound.

4. (Amended) The method of claim 1, wherein the polypeptide of interest has been modified by the addition of the FLAsH target sequence motif [C C X<sub>1</sub> X<sub>2</sub> C C] C-C-X<sub>1</sub>-X<sub>2</sub>-C-C (SEQ ID NO:1), where X<sub>1</sub> and X<sub>2</sub> are any amino acid.

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8. (Amended) The method of claim 1, wherein said solid support is selected from the group consisting of agarose, polyacrylimide, glass, ceramics, natural or synthetic polymeric materials, beads, coverslips, paper, metals, metalloids, polacryloylmorpholide, various plastics and plastic copolymers such as a Nylon<sup>TM</sup> copolymer, a Teflon<sup>TM</sup> copolymer, polyethylene, polypropylene, poly(4-methylbutene), polystyrene, polystyrene, polystyrene/latex, polymethacrylate, poly(ethylene terephthalate), rayon, nylon, poly(vinyl butyrate), polyvinylidene difluoride (PVDF), silicones, polyformaldehyde, cellulose, cellulose acetate, nitrocellulose, and controlled-pore glass, aerogels, and affinity exchange resins.